**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 24, 2015

SAEYANG MICROTECH CO., LTD.
c/o Ms. Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave., Suite 110
Fullerton, CA 92831

Re: K141482
Trade/Device Name: Ki-20
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: March 20, 2015
Received: March 23, 2015

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,


for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
k141482

Device Name

Ki-20

Indications for Use *(Describe)*

For use in a wide range of dental procedures including; endodontic surgeries, such as drilling into the tooth canal, and general dentistry, such as removing carious material from the dentin.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary
(k141482)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Apr 24, 2015

**1. 510K Applicant / Submitter:**

Saeyang Microtech Co., Ltd.
348, Seongseo-ro, Dalseo-gu, Daegu
704-900 REPUBLIC OF KOREA
Tel: +82-53-582-9000~2
Fax: +82-53-581-9003

**2. Submission Contact Person**

LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110, Fullerton, CA 92831
Priscilla Juhee Chung
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

**3. Device**

- Proprietary Name: Ki-20
- Common Name: Dental Handpiece and Accessories
- Classification Name: Controller, Foot, Handpiece and Cord
- Regulatory Class: Class I
- Product Code: EBW
- Classification Regulation: 21 CFR 872.4200

**4. Predicate Device**

- **Primary Predicate Device:**
  Endo E Class by Saeyang Microtech Co., Ltd. (K123608)

- **Reference Predicate Devices:**
  TRAUS SIP10 by Saeshin Precision Co., Ltd. (K123695)
  X-CUBE by Saeshin Precision Co., Ltd. (K092758)

**5. Description:**

The Ki-20 is designed to use in dental surgery. It consists of an E-type motor (DC 28V Operation Motor), handpieces, a control box, a foot switch and other accessories. It is designed that the speed and direction of the handpiece can be controlled by the control box and the foot switch. The irrigation tube and the pump are used to supply the cooling water for the successful surgery.

**8. Indications for Use**

For use in a wide range of dental procedures including: endodontic surgeries, such as drilling into the tooth canal, and general dentistry, such as removing carious material from the dentin.

**9. Substantial Equivalence Discussion:**

Ki-20 is substantially equivalent to Endo E Class (K123608), TRAUS SIP10 (K123695) and X-CUBE (K092758). The following comparison table is presented to demonstrate substantial equivalence.
Ki-20 does not have a new intended use and it shows equivalent specifications with the predicate devices in most of parameters. The handpiece rotation speed of the subject device encompasses the subject device as well.
Torque setting range applied to the motor of the subject device is different from the predicate device; however, it is within what was cleared in the reference devices.

| | **Candidate Device** | **Primary Predicate Device** | **Reference Predicate Device** | **Reference Predicate Device** |
|---|---|---|---|---|
| **510(k) Number** | K141482 | K123608 | K123695 | K092758 |
| **Device Name** | Ki-20 | Endo E Class | TRAUS SIP10 | X-CUBE |
| **Common Name** | Dental Handpiece and accessories | Dental Handpiece and accessories | Dental Handpiece and accessories | Surgical motor unit for implantology and maxilla surgery |
| **Manufacturer** | Saeyang Microtech Co., Ltd. | Saeyang Microtech Co., Ltd. | Saeshin Precision Co., Ltd. | Saeshin Precision Co., Ltd. |
| **Intended Use** | For use in a wide range of dental procedures including; endodontic surgeries, such | For use in a wide range of dental procedures including; endodontic surgeries, such | The TRAUS SIP 10 is intended for use in dental surgery, implantology, maxilla-facial | The X-CUBE is intended for use in dental surgery, implantology, maxilla-facial surgery and |

| | | | | |
|---|---|---|---|---|
| | as drilling into the tooth canal, and general dentistry, such as removing carious material from the dentin. | as drilling into the tooth canal, and general dentistry, such as removing carious material from the dentin. | surgery and endodontics for treatment of dental hard tissue and mechanical rotating root canal preparation | endodontics for treatment of dental hard tissue and mechanical rotating root canal preparation |
| **Micromotor drive** | Electric micromotor drive | Electric micromotor drive | Electric micromotor drive | Electric micromotor drive |
| **Package contents** | Power cord, Control unit, Irrigation tube, Y-tube, Tube holder, Coolant hanger, Foot control, handpiece stand, E-type motor&Motor cord, Foot hanger, Contra angle, E-type spray nozzle, External spray nozzle, Nozzle clamp, Internal spray nozzle | Control Unit, E-type Motor & Motor Cord, E-type Handpiece, foot switch, Handpiece stand, Power Cord, Autoclaving Plugs, Manual | Hanger, Foot controller, Control box, Power cord, Motor stand, Irrigation tube, Internal spray nozzle, Motor cap for autoclave, Angle handpiece, BLDC motor, Tube holder, Tube clamp, Y-tube, Foot hanger, Foot hanger joint cap, Instruction Manual | Hanger, Foot controller, Control box, Power cord, Motor stand, Irrigation tube, Internal spray nozzle, Motor cap for autoclave, Angle handpiece, BLDC motor, Tube holder, Tube clamp, Y-tube, Foot hanger |
| **Patient Contacting Part's Material** | Stainless Steel & BSBM | Stainless Steel & BSBM | Stainless Steel & BSBM | Stainless Steel & BSBM |
| **Handpiece chuck** | Push button & handle type | Push button & handle type | Push button & handle type | Push button & handle type |
| **Coolant Motor** | DC motor | No | DC motor | DC motor |
| **Shank length & Type** | Shank length : 11mm(Type 1 Shank) | Shank length : 11mm(Type 1 Shank) | Shank length : 11mm(Type 1 Shank) | Shank length : 11mm(Type 1 Shank) |
| **Operation Principle** | Speed control, Torque control, Program Memory | Speed control, Torque control, Program Memory | Speed control, Torque control, Program Memory | Speed control, Torque control, Program Memory |

| | | | | |
|---|---|---|---|---|
| **Motor speed range** | 600~40,000rpm | 20~17500rpm | 0~40,000 rpm | 600~50,000 rpm |
| **Handpiece rpm range** | 20 ~ 80,000 rpm | 20~17,500rpm | 10~200,000rpm | 10~200,000rpm |
| **Torque setting range applied to the motor in Ncm** | 5~65Ncm | 0.1~9.9Ncm | 5~65Ncm | 5~65Ncm |
| **Allows reciprocating drive (forward/reverse cycling)** | Yes | Yes | Yes | Yes |
| **Allows selection of gear ratios for different geared E-type handpieces** | 1:1, 1:2, 20:1, 32:1 | 1:1, 4:1, 6:1, 8:1, 10:1, 16:1, 20:1, 64:1 | 1:5, 1:4, 1:1, 16:1, 20:1, 27:1, 32:1, 64:1 | 1:5, 1:4, 1:1, 16:1, 20:1, 27:1, 32:1, 64:1 |
| **Allows selection of forward or Auto reverse drive rotation** | Yes | Yes | Yes | Yes |
| **Allows selection of Auto stop** | Yes | Yes | Yes | Yes |
| **Allows use of a foot switch control to operate the attached handpiece motor** | Yes Electronic foot control | Yes Electronic foot control | Yes Electronic foot control | Yes Electronic foot control |
| **Allows the user to define their own presets for speed and torque** | Yes | Yes | Yes | Yes |
| **Allows programmable doctor's choice** | Yes | Yes | Yes | Yes |
| **Input voltage(charger)** | AC100V~120V, 50/60Hz AC220V~240V, 50/60Hz | AC100V~120V, 50/60Hz AC220V~240V, 50/60Hz | AC100V~120V, 50/60Hz AC220V~240V, 50/60Hz | AC100V~120V, 50/60Hz AC220V~240V, 50/60Hz |
| **Handpiece Coupling type** | E-type | E-type | E-type | E-type |
| **Lubricant** | NSK PANA SPRAY PLUS | NSK PANA SPRAY PLUS | Information not available | Information not available |

| | | | | |
|---|---|---|---|---|
| | (K131014) | (K131014) | | |

**10. Performance Tests (Non-clinical)**

Non-clinical bench tests were performed as followings:

- ISO 3964:2014 Dental Handpieces - Coupling dimensions
- ISO 7494-1:2004 Dentistry - Dental units -Part 1: General requirements and test methods
- ISO 14457:2012 Dentistry - Handpieces and motors
- IEC 60601-1, IEC 60601-1-2, IEC61000-3-2, IEC61000-3-3: Electrical safety and EMC

Along with the above tests, the following tests were performed:

- Sterilization validation in accordance with ISO 11135-1, ISO 11138-1, ISO 11138-3, ISO 11607-1, ISO 17664, ISO 17665-1, and ISO 17665-2
- Software validation in accordance with the FDA Guidance, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff"
- Usability test EN60601-1-6, EN 62366 and IEC 62366
- Temperature rise testing

None of the testing demonstrated any design characteristics that violated the requirements of the standards or resulted in any safety hazard.

**11. Conclusions:**

Based on the information provided in this premarket notification, Saeyang Microtech Co., Ltd. concludes that the Ki-20 is substantially equivalent to the predicate device as described herein in.